BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2015-0048]

Monsanto Co.; Availability of a Preliminary Plant Pest Risk Assessment, Draft Environmental Assessment, Preliminary Finding of No Significant Impact, and Preliminary Determination of Nonregulated Status for Maize Genetically Engineered for Resistance to Dicamba and Glufosinate

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared a preliminary determination regarding a request from Monsanto Co. seeking a determination of nonregulated status for maize designated as event MON 87419, which has been genetically engineered for resistance to the herbicides dicamba and glufosinate. We are also making available for public review and comment our preliminary plant pest risk assessment, draft environmental assessment, and preliminary finding of no significant impact for the preliminary determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [**INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER**].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0048.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2015-0048, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents for this petition and any comments we receive on this docket may be viewed at http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0048 or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

Supporting documents for this petition are also available on the APHIS Web site at http://www.aphis.usda.gov/biotechnology/petitions_table_pending.shtml under APHIS Petition Number 15-113-01p.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Biotechnology Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147, Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the petition, contact Ms. Cindy Eck at (301) 851-3892, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Under the authority of the plant pest provisions of the Plant Protection Act (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or

produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered (GE) organisms and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. APHIS received a petition (APHIS Petition Number 15-113-01p) from the Monsanto Company (Monsanto) of St. Louis, MO, seeking a determination of nonregulated status of maize (Zea mays) designated as event MON 87419, which has been genetically engineered for resistance to the herbicides dicamba and glufosinate. The Monsanto petition states that information collected during field trials and laboratory analyses indicates that MON 87419 maize is not likely to be a plant pest and therefore should not be a regulated article under APHIS' regulations in 7 CFR part 340.

According to our process[1] for soliciting public comment when considering petitions for determinations of nonregulated status of GE organisms, APHIS accepts written comments regarding a petition once APHIS deems it complete. In a notice[2] published in the **Federal Register** on August 13, 2015 (80 FR 48489-48490, Docket No. APHIS-2015-0048), APHIS announced the availability of the Monsanto petition for public comment. APHIS solicited comments on the petition for 60 days ending on October 13, 2015, in order to help identify potential environmental and interrelated economic issues and impacts that APHIS may determine

[1] On March 6, 2012, APHIS published in the **Federal Register** (77 FR 13258-13260, Docket No. APHIS-2011-0129) a notice describing our public review process for soliciting public comments and information when considering petitions for determinations of nonregulated status for GE organisms. To view the notice, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2011-0129.

[2] To view the notice, the petition, and the comments we received, go to http://www.regulations.gov/#!docketDetail;D=APHIS-2015-0048.

should be considered in our evaluation of the petition. APHIS received 21 comments on the petition, one of which included over 23,000 signatures opposing the petition. APHIS has evaluated the issues raised during the comment period and, where appropriate, has provided a discussion of these issues in our draft environmental assessment (EA).

After public comments are received on a completed petition, APHIS evaluates those comments and then provides a second opportunity for public involvement in our decisionmaking process. According to our public review process (see footnote 1), the second opportunity for public involvement follows one of two approaches, as described below.

If APHIS decides, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises no substantive new issues, APHIS will follow Approach 1 for public involvement. Under Approach 1, APHIS announces in the **Federal Register** the availability of APHIS' preliminary regulatory determination along with its draft EA, preliminary finding of no significant impact (FONSI), and its preliminary plant pest risk assessment (PPRA) for a 30-day public review period. APHIS will evaluate any information received related to the petition and its supporting documents during the 30-day public review period. For this petition, we are using Approach 1.

Had APHIS decided, based on its review of the petition and its evaluation and analysis of comments received during the 60-day public comment period on the petition, that the petition involves a GE organism that raises substantive new issues, APHIS would follow Approach 2. Under Approach 2, APHIS first solicits written comments from the public on a draft EA and preliminary PPRA for a 30-day comment period through the publication of a **Federal Register** notice. Then, after reviewing and evaluating the comments on the draft EA and preliminary

PPRA and other information, APHIS would revise the preliminary PPRA as necessary and prepare a final EA and, based on the final EA, a National Environmental Policy Act (NEPA) decision document (either a FONSI or a notice of intent to prepare an environmental impact statement).

As part of our decisionmaking process regarding a GE organism's regulatory status, APHIS prepares a PPRA to assess the plant pest risk of the article. APHIS also prepares the appropriate environmental documentation—either an EA or an environmental impact statement—in accordance with NEPA, to provide the Agency and the public with a review and analysis of any potential environmental impacts that may result if the petition request is approved.

APHIS has prepared a preliminary PPRA and has concluded that maize designated as event MON 87419, which has been genetically engineered for resistance to the herbicides dicamba and glufosinate, is unlikely to pose a plant pest risk. In section 403 of the Plant Protection Act, "plant pest" is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant or plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing.

APHIS has also prepared a draft EA in which we present two alternatives based on our analysis of data submitted by Monsanto, a review of other scientific data, field tests conducted under APHIS oversight, and comments received on the petition. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of maize designated as event MON 87419, or (2) make a determination of nonregulated status of maize designated as event MON 87419.

The draft EA was prepared in accordance with (1) NEPA, as amended (42 U.S.C. 4321 et seq.), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). Based on our draft EA and other pertinent scientific data, APHIS has prepared a preliminary FONSI with regard to the preferred alternative identified in the draft EA.

Based on APHIS' analysis of field and laboratory data submitted by Monsanto, references provided in the petition, peer-reviewed publications, information analyzed in the draft EA, the preliminary PPRA, comments provided by the public on the petition, and discussion of issues in the draft EA, APHIS has determined that maize designated as event MON 87419 is unlikely to pose a plant pest risk. We have therefore reached a decision to make a preliminary determination of nonregulated status of maize designated as event MON 87419, whereby maize designated as event MON 87419 would no longer be subject to our regulations governing the introduction of certain GE organisms.

We are making available for a 30-day review period APHIS' preliminary regulatory determination of maize designated as event MON 87419, along with our preliminary PPRA, draft EA, and preliminary FONSI for the preliminary determination of nonregulated status. The draft EA, preliminary FONSI, preliminary PPRA, and our preliminary determination for maize designated as event MON 87419, as well as the Monsanto petition and the comments received on the petition, are available as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained from the person listed under FOR FURTHER INFORMATION CONTACT.

After the 30-day review period closes, APHIS will review and evaluate any information received during the 30-day review period. If, after evaluating the information received, APHIS determines that we have not received substantive new information that would warrant APHIS altering our preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the draft EA, or substantially changing the analysis of impacts in the draft EA, APHIS will notify the public through an announcement on our Web site of our final regulatory determination. If, however, APHIS determines that we have received substantive new information that would warrant APHIS altering our preliminary regulatory determination or FONSI, substantially changing the proposed action identified in the draft EA, or substantially changing the analysis of impacts in the draft EA, then APHIS will conduct the additional analysis and prepare an amended EA, a new FONSI, and/or a revised PPRA, which would be made available for public review in a subsequent notice in the **Federal Register**, similar to an Approach 2 petition. APHIS will also notify the petitioner.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 10th day of February 2016.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

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